

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,730	01/17/2002	Brooks Edwards	9550-001-27	2580
23552 7590 12/19/2006 MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903		,	EXAMINER	
		· · · · · · · · · · · · · · · · · · ·	CEPERLEY, MARY	
			ART UNIT	PAPER NUMBER
		•	1641	
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	
3-MO	NTHS	12/19/2006	PAP	ER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)			
	10/046,730	EDWARDS ET AL.			
Office Action Summary	Examiner	Art Unit			
	Mary (Molly) E. Ceperley	1641			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 16(a). In no event, however, may a reply be tim rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. sely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status		,			
1) Responsive to communication(s) filed on 18 Se	eptember 2006.				
2a) ☐ This action is FINAL . 2b) ☑ This					
3) Since this application is in condition for allowar	application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	53 O.G. 213.			
Disposition of Claims		·			
4) □ Claim(s) 1,3,7-9,11-22,24-26,28-31 and 69-74 4a) Of the above claim(s) is/are withdrav 5) □ Claim(s) is/are allowed. 6) □ Claim(s) 1,3,7-9,11-22,24-26, 28-31 and 69-74 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and/or	vn from consideration. is/are rejected.				
Application Papers					
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the Replacement drawing sheet(s) including the correction 11) The oath or declaration is objected to by the Examine 11.	epted or b) objected to by the Edrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priorical application from the International Bureau * See the attached detailed Office action for a list of the certified copies.	s have been received. s have been received in Applicati ity documents have been receive ı (PCT Rule 17.2(a)).	on No ed in this National Stage			
Attachment(s)	_				
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date シンナルル	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate			

Art Unit: 1641

- 1) The structure of claim 69 is missing a terminal group. Correction is required.
- 2) Although specific claims may be discussed in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.
- *3)* The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 4) Claims 72-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no written description in the specification to support the configuration of claim 72, namely the configuration wherein the immobilized probes are "attached to a first surface" while the "chemiluminescent quantum yield enhancing material" is present "on a second surface of the support opposite the first surface of the support". Applicants cite page 22, lines 5-14 of the specification as support for this limitation {Remarks, page 16}. However, this section of the specification describes the enhanced migration of the dioxetane anion through the support structure in the presence of the enhancer but says nothing about the positioning of the enhancers and probes relative to each other and the surface. Similarly, none of the sections of the specification cited in the second paragraph of page 15 of the Remarks relates to the configuration described in claim 72.
- *5)* The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d

Art Unit: 1641

887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6) Claims 1, 3, 7-9, 11-22, 24-26, 28-31 and 69-74 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 and 58 of copending Application No. 10/462,742. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to surface arrays having defined "discrete areas" (or "spatially defined regions) containing chemiluminescent enhancing material or a plurality of probes. Although claim 1 of 10/046,730 requires that the chemiluminescent enhancing material be present "in spatially defined regions" while claim 1 of 10/462,730 requires that the probes be located "plurality of discrete areas", the open-ended "comprising" terminology used in both applications is inclusive of arrays having either the probe or the enhancer, or both, in "spatially defined regions" (equivalent to "plurality of discrete areas"). Claim 1 of 10/046,730 also encompasses the particular "density of discrete areas" recited in claim 1 of 10/462,742. The limitation that the enhancer is "on the surface" is present in claim 1 of each of 10/462,742 and 10/046,730; this limitation is inclusive of the "covalent attachment" of the enhancer as recited in claim 26 of 10/046,730.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3, 7-9, 11-22 and 24 are rejected under 35 U.S.C. 103(a) as being obvious over a) each of Bronstein et al {US 5,849,495} and Bronstein et al {US 5,336,596} taken in combination with b) each of Matson et al {US 5,981,185} or Anderson et al {US 2001/0012537 A1}.

Art Unit: 1641

Bronstein et al {US 5,849,495} and Bronstein et al {US 5,336,596} are applied for the reasons set forth in paragraphs *12*) and *13*) respectively of the May 03, 2004 Office action.

Matson et al and Anderson et al are each applied to establish that two dimensional microarrays composed of discrete areas (or "spatially defined regions") containing analytical reagents are well known for use in biological ligand binding assays. See Matson et al: col. 3, lines 39-41; col. 6, lines 16-21; Anderson et al: paragraphs [0146] and [0011].

Given the fact that *1)* quaternary onium polymers are well known chemiluminescence-enhancing agents which are used as coatings on solid supports used in biological assays {Bronstein et al '495 and Bronstein et al '596} and given the fact that *2)* the use of the microarray format composed of solid supports containing reagents in discrete areas (or "spatially defined regions") is well known in the biological assay art {Matson et al and Anderson et al}, it is considered to be a routine modification which is well within the skill of the art and therefore obvious to modify the Bronstein et al supports to contain the assay reagents in microarray format, as claimed.

The features of the dependent claims are either specifically described by the references or constitute obvious variations in parameters which are routinely modified in the art and which have not been described as critical to the practice of the invention. For example, for the nucleic acid and protein probes of claims 7 and 8, see Bronstein et al {495}, col. 7, lines 33-37; for the enhancer of claim 3, see Bronstein et al {495}, formula (I) of col. 10 wherein each of R¹, R² and R³ is "a straight or branched chain unsubstituted alkyl having from 1 to 20 carbon atoms".

8) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 07, 2006

Mary E. Ceperley

Mary (Molly) E. Ceperley

Primary Examiner Art Unit 1641